

**REMARKS**

**I. Status of the Claims**

Claims 24, 25, 28-31, and 37-51 are pending in this application. Claims 26 and 27 were previously canceled and claims 32-36 are currently canceled. Claims 40-51 are new and have been added to comply with the Examiner's suggestion to rewrite claims 33-35 in independent form. Specifically, new claims 40-43 correspond with previous claims 32-36 and new claims 44-51 are dependent indirectly or directly on new claim 40. Thus, no new matter has been introduced by this amendment, nor is any additional search by the Office thereby necessitated.

Applicants acknowledge and appreciate the Examiner's withdrawal of the 35 U.S.C. § 112, second paragraph, rejection and the 35 U.S.C. § 103 rejection over *San-Doz* in view of *Van Scott*.

**II. Rejections Under 35 U.S.C. § 102(b)**

Claims 24, 25, 28, 29, and 32 stand rejected under 35 U.S.C. § 102(b) as anticipated by EP 0 435 436 ("*Francoeur*") and claims 24, 25, 28, 29, 32, 37, and 38 as anticipated by U.S. Patent No. 5,376,646 ("*Pittrof*"). Applicants respectfully submit, however, that neither reference anticipates the claims of this application because the elements of the claims are not taught clearly and unequivocally by the cited references. Applicants respectfully traverse this rejection for at least the following reasons.

For anticipation to be proper a reference must show the "identical" invention "in as complete detail as is contained in the ... claim[s]." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Further, without the

need for picking, choosing, and combining various disclosures, the reference must direct those skilled in the art to the invention. *In re Arkley*, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972). Neither *Francoeur* nor *Pittrof* fulfills these requirements.

The Examiner contends that *Francoeur* anticipates the claims of the present invention because it teaches the topical administration of a pharmaceutical agent (azithromycin), an aqueous solvent and a dermal penetration enhancer (oleic acid). The Examiner has not shown, however, that the composition of *Francoeur* when applied to the skin produces a "minimal systemic effect" as the claims of this application recite. To the contrary, *Francoeur* teaches that "the drug is 'phoresed' from the solution across the dermal barrier and into the local tissue (to produce high local tissue levels of the drug), or given enough time and other appropriate conditions, into the blood stream, whereby the drug is delivered systemically to more remote site(s) of action." (*Francoeur*, page 2, lines 11-14.) Accordingly, because *Francoeur* does not teach each and every element of Applicants' claims, the claims are not anticipated.

The Examiner further contends that *Pittrof* teaches a topical preparation containing cholanolic acid and a lipid, which may also contain active substances, such as antibiotics, and adjuvants and other additives, such as oleic acid, paraffins, and solvents. This combination of components, however, is not clearly and unequivocally taught by *Pittrof*, nor are all elements of Applicants' claims. For example, one would have to select the Examiner's proposed combination of components from the numerous pharmaceutically active compounds disclosed and the numerous additives recited by *Pittrof*. (*Pittrof*, col. 1, line 48 through col. 2, line 14 and col. 2, lines 51-63.) Further,

not one of the examples employs FK 506 or any other claimed antibiotic or immunosuppressive macrolide. Additionally, *Pittrof* mentions increased penetration of the skin but fails to teach that its compositions produce a "minimal systemic effect" in practice because the reference is silent as to whether the active agents, which are optional (*Pittrof*, col. 3, lines 17-24), penetrate so far as to induce a systemic effect. (*Pittrof*, col. 1, lines 12-15.) Thus, the elements of the instant claims are not clearly and unequivocally taught by *Pittrof*.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections over *Francoeur* and *Pittrof*.

### III. Rejection Under 35 U.S.C. § 103(a)

Claims 24, 25, 28-32, and 36-39 stand rejected as unpatentable under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 5,376,646 ("*Pittrof*") and International Publication No. 96/13249 ("*Sandoz*"). The Examiner alleges that *Pittrof* teaches the claimed elements but for the topical use of the composition to treat the claimed dermatological conditions and, thus, relies on *Sandoz* to cure this deficiency. In particular, the Examiner alleges that it would have been obvious to one of ordinary skill in the art to administer the composition of *Pittrof* to treat the claimed dermatological conditions because *Sandoz* teaches the treatment of inflammatory and hyperproliferative skin diseases. Applicants respectfully traverse this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness there must be a suggestion or motivation to combine the reference teachings and the combination must teach or

suggest the elements of the claims. M.P.E.P. § 2143. Here, there is no motivation to make the Examiner's proposed combination nor are all elements thereby taught.

As Applicants explained above, *Pittrof* fails to teach each and every element of the claims because one would have to select the Examiner's proposed combination of components from the numerous additives and pharmaceutically active compounds disclosed by *Pittrof*. Additionally, *Pittrof* fails to teach that its compositions produce a "minimal systemic effect." The Examiner has not shown that *Sandoz* remedies these deficiencies. In addition, the combination of the two references does not take into account the components of *Pittrof*, such as the cholanic acid and lipid, and the possible effect these components would have in practice. To the contrary, the Examiner has not shown that the composition of *Pittrof* could be used to treat any dermatological condition at all and the Examiner has not provided any reason for why the proposed combination of references would have been obvious. Thus, the Examiner has not provided clear and particular evidence that it would have been obvious to one of ordinary skill in the art to have made the proposed substitution.

Therefore, as no *prima facie* case of obviousness has been established, Applicants respectfully request withdrawal of this 35 U.S.C. § 103 rejection.

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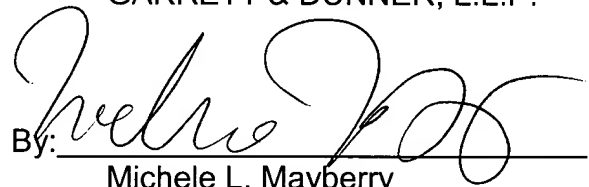
IV. Conclusion

In view of the foregoing amendment and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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